

## REMARKS

Claims 22-26 and 70-87 are pending. Claims 22-26 are withdrawn from consideration and claims 70-87 are rejected. No claims have been allowed.

The present invention provides a gamma irradiated sterilized therapeutic composition comprising microparticles comprising at least one polymer and at least one therapeutically active agent wherein said microparticles are gamma irradiated at a temperature of less than 25 C. to thereby provide microparticles that are less aggregated than when the same therapeutic composition is gamma irradiated for the same time and at the same dose of gamma radiation at a temperature greater than 5 C.

The Examiner has rejected all of the claims, except for the claims which are specific as to the therapeutically active agent being tazarotene, under 35 USC 102 for lack of novelty over Tice et al, Rodgers and Montari.

It is believed that the present amendment overcomes these rejections by limiting the claimed sterilized therapeutic compositions to those prepared by gamma irradiating at a temperature of less than 25 C. to thereby provide microparticles that are less aggregated than when the same therapeutic composition is gamma irradiated for the same time and at the same dose of gamma radiation at a temperature greater than 5 C. It is this discovery that gamma irradiating at a temperature of less than 25 C. results in the preparation of microparticles that are less aggregated than when the same therapeutic composition is gamma irradiated for the same time and at the same dose of gamma radiation at a temperature greater than 5 C.

The above references cited by the Examiner do not recognize this phenomena, explicitly, nor do these references inherently carry out the sterilization with gamma radiation at the claimed temperature. Therefore the rejection under 35 USC 102 is now overcome by the present amendment.

Nor is there any disclosure in said references that would suggest the discovery made and claimed in the present claims. Therefore, there is no basis for making a rejection under 35 USC 103. That is the presently amended claims are unobvious over the above references.


The Examiner's rejection under 35 USC 103 over the above references in further combination with Perricone, which discloses that tazarotene is a retinoid, fails for the same reason the above references fail, i.e. there is no teaching that gamma irradiation at a temperature of less than 25 C. would provide microparticles that are less aggregated than if the same therapeutic composition was gamma irradiated for the same time and at the same dose of gamma radiation at a temperature greater than 5 C.

Finally, the applicants wish to point out that they are not relying on particle size to distinguish their invention over the prior art. In fact claims 86 and 87 have been cancelled to emphasize this. It is the discovery that gamma irradiation at a temperature of less than 25 C. provides microparticles that are less aggregated than if the same therapeutic composition was gamma irradiated for the same time and at the same dose of gamma radiation at a temperature greater than 5 C., that is the basis for their invention.

It is believed that the claims, as presently amended, are patentable over the prior art. Applicants hereby request that the Examiner withdraw the outstanding rejection and pass the claims, as amended, to issue.

The undersigned is an attorney of record.

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